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## BISNIS Search for Partners – Leads from the BioIndustry Initiative

**INDUSTRY:**  
**MEDICAL  
EQUIPMENT AND  
PRODUCTS,  
PHARMACEUTICALS,  
HEALTH CARE  
SERVICES**

**COMPANY /  
INSTITUTE:**  
State Research Institute  
of Highly Pure  
Biopreparations, St.  
Petersburg  
[www.hpb-spb.com](http://www.hpb-spb.com)

**COUNTRY:** Russian  
Federation

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## **AEROSOL DELIVERY OF RECOMBINANT RECEPTOR ANTAGONIST OF INTERLEUKIN-1 (ARIL) FOR THE TREATMENT OF INFLAMMATORY, AUTOIMMUNE, AND ALLERGIC DISEASES**

**ABSTRACT:** A number of pathologies are associated with hyperproduction of interleukin-1 (IL-1). A balance between local interleukin-1 and interleukin-1 receptor antagonist (IL-1ra) is important for regulating potentially dangerous effects of IL-1. Multiple positive effects of IL-1ra in treating inflammatory, allergic, and autoimmune diseases were demonstrated in experimental animals. Among these are rheumatoid arthritis, psoriatic rheumatoid arthritis, granulomatosis pulmonary diseases, myasthenia gravis, asthma, traumas, brain injuries, and others. Highly Pure has developed a pilot technology for the manufacture of recombinant human IL-1ra bulk substance. Phase II clinical trials of IL-1ra injections in the therapy of rheumatoid arthritis are currently underway. We are also developing a novel form of the drug for application in the form of aerosols. The specific activity of aerosolized IL-1ra is currently being studied. We have found that aerosolized IL-1ra (as compared to injection analogs) is more efficient and with reduced side effects for treatment of pulmonary and other diseases.

**TYPE OF PARTNERSHIP OFFERED:** Highly Pure seeks partnerships with potential investors and pharmaceutical companies for scaling up of IL-1ra manufacture and conducting clinical trials of aerosolized IL-1ra for regulatory approvals in major global markets.

**COMPANY / INSTITUTE ROLE:** Partnership on clinical trials design, provision of preclinical and clinical data sets, licensing of manufacturing process / methods.

**CURRENT STATE OF DEVELOPMENT:** Phase II clinical trials of IL-1ra injections in the therapy of rheumatoid arthritis and psoriatic rheumatoid arthritis are currently underway. Partnership on clinical trials design, provision of preclinical and clinical data sets, licensing of manufacturing process / methods.

## OTHER INFORMATION

Institute representatives will be attending BIO2006 (Chicago, April 9 – 12, 2006) and welcome the opportunity to meet with interested parties during the event. For more information:

<http://www.biistate.net/docs/bio2006.php> or email:

[EurasiaBio2006@biistate.net](mailto:EurasiaBio2006@biistate.net)

**INTELLECTUAL PROPERTY STATUS:** A patent application for the method of manufacture of recombinant human IL-1ra bulk substance has been filed.

## ABOUT THE INSTITUTE:

Highly Pure specializes in novel therapeutics and diagnostics based on immunological principles: particularly, the production of cytokines and peptides of medical interest; novel drug delivery systems; new adsorption materials for purification of proteins and extracorporeal therapy. Highly Pure's staff includes 300 highly skilled biologists, physicists, chemists, physicians, mathematicians and engineers. The Institute has pilot production facilities that are certified by the Russian Ministry of Health and Social Development to manufacture drugs based on its proprietary gene-engineered proteins and synthetic peptides. This facility is currently being upgraded to comply with international cGMP. Highly Pure manufactures the following biopharmaceuticals for domestic and near-abroad markets:

- Betaleukin® – the world's first drug based on the recombinant human interleukin-1 $\beta$  for oncology, infectious diseases and for protection from radiation;
- Epocrin® - based on recombinant human erythropoietin, for therapy of oncologic and infectious diseases;
- Interalf® – based on recombinant human interferon  $\alpha$ -2a, for therapy of oncologic and infectious diseases
- Allokin-alpha® – synthetic peptide-based drug for the treatment of genital Herpes and other viral diseases;
- Glutoxim® - synthetic peptide-based immunostimulatory drug for the therapy of oncologic and infectious diseases;
- Bestim® - immunostimulatory peptide-based drug for therapy of infectious diseases and for protection from radiation.
- Vitaflor™ – a complex bacterial preparation for prophylaxis and treatment of dysbacteriosis
- Chitoskin™ – biodestructable wound healing bandages based on chitosan and collagen for the therapy of wounds, burns, ulcers, and skin inflammations

## MAJOR CUSTOMERS / INTERNATIONAL EXPERIENCE:

Biopharmaceuticals manufactured by Highly Pure for domestic and near-abroad markets are sold through the major pharmaceutical products distributors on those territories. Researchers at the Highly Pure are collaborating with scientists at top universities in the U.S., such as the Yale University School of Medicine, the University of North Carolina, and the University of California at Berkeley, the National Institute of Health, and the Massachusetts General Hospital, among others. Highly Pure has extensive experience with international grants from organizations such as the International Science & Technology Center ([www.istc.ru](http://www.istc.ru)) and the US Civilian Research & Development Foundation ([www.crdf.org](http://www.crdf.org)).

**PARTNERSHIP OPPORTUNITIES FROM BII.** The BioIndustry Initiative (BII) is a nonproliferation program of the US Department of State's Bureau of International Security and Nonproliferation - Office of Cooperative Threat Reduction (ISN-CTR). BII's mission is to counter the threat of bioterrorism through targeted transformation of former Soviet biological weapons research and production capacities.

**DISCLAIMER.** The leads are sourced by the BioIndustry Initiative through our partner organizations in Russia and other Eurasian countries. Leads are provided solely as an information resource and do not represent an endorsement by BII or the U.S. Departments of State and Commerce. Verification of the leads is the responsibility of the reader. Assistance conducting due diligence and negotiations with Eurasian companies/institutes may be provided in some cases. Contact BII for more details: [bii@biistate.net](mailto:bii@biistate.net).